UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

X **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2005

OR

___ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to _____

Commission file number: **0-19825**

SCICLONE PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**94-3116852**
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer Identification no.)
901 Mariner's Island Blvd., Suite 205, San Mateo, California	**94404**
(Address of principal executive offices)	(Zip code)

(650) 358-3456
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ____X_____ No _____

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes ____X_____ No _____

As of July 29, 2005, 45,708,548 shares of the registrant's Common Stock, $0.001 par value, were issued and outstanding.

SCICLONE PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

SCICLONE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2005 (unaudited)	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,265,000	$ 41,204,000
Restricted short-term investments	693,000	700,000
Other short-term investments	9,457,000	9,395,000
Accounts receivable, net of allowance of $447,000 in 2005 and $452,000 in 2004	9,204,000	10,279,000
Inventories	3,550,000	4,179,000
Prepaid expenses and other current assets	1,149,000	1,478,000
Total current assets	63,318,000	67,235,000
Property and equipment, net	376,000	398,000
Intangible assets, net	507,000	542,000
Other assets	1,518,000	1,534,000
Total assets	$ 65,719,000	$ 69,709,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 375,000	$ 1,733,000
Accrued compensation and employee benefits	1,544,000	2,177,000
Accrued professional fees	543,000	452,000
Other accrued expenses	2,025,000	1,409,000
Accrued clinical trials expense	1,470,000	1,500,000
Deferred revenue	403,000	537,000
Convertible notes payable	5,600,000	4,000,000
Total current liabilities	11,960,000	11,808,000
Deferred revenue	--	134,000
Other long-term liabilities	500,000	1,044,000
Convertible note payable	--	1,600,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $0.001 par value; 10,000,000 shares authorized; no shares outstanding	--	--
Common stock; $0.001 par value; 75,000,000 shares authorized; 45,335,548 and 44,677,845 shares issued and outstanding in 2005 and 2004, respectively	45,000	45,000
Additional paid-in capital	207,740,000	206,608,000
Accumulated other comprehensive income	41,000	38,000
Accumulated deficit	(154,567,000)	(151,568,000)
Total stockholders' equity	53,259,000	55,123,000
Total liabilities and stockholders' equity	$ 65,719,000	$ 69,709,000

See notes to condensed consolidated financial statements

SCICLONE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Product sales	$ 6,851,000	$ 5,613,000	13,512,000	$ 11,027,000
Contract revenue	134,000	1,135,000	268,000	1,363,000
Total revenues	6,985,000	6,748,000	13,780,000	12,390,000
Cost of product sales	1,166,000	1,178,000	2,163,000	2,320,000
Gross margin	5,819,000	5,570,000	11,617,000	10,070,000
Operating expenses:				
Research and development	3,479,000	5,145,000	6,960,000	9,076,000
Sales and marketing	2,432,000	2,148,000	4,760,000	4,591,000
General and administrative	1,588,000	1,156,000	3,208,000	2,449,000
Total operating expenses	7,499,000	8,449,000	14,928,000	16,116,000
Loss from operations	(1,680,000)	(2,879,000)	(3,311,000)	(6,046,000)
Interest and investment income	286,000	112,000	519,000	228,000
Interest expense	(91,000)	(91,000)	(181,000)	(181,000)
Other income (expense), net	(20,000)	(19,000)	(26,000)	(11,000)
Net loss	$ (1,505,000)	$ (2,877,000)	(2,999,000)	$ (6,010,000)
Basic and diluted net loss per share	$ (0.03)	$ (0.06)	(0.07)	$ (0.13)
Weighted average shares used in computing basic and diluted net loss per share	45,002,383	44,612,260	44,851,916	44,590,674

See notes to condensed consolidated financial statements

SCICLONE PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Six Months Ended June 30,	
	2005	**2004**
Operating activities:		
Net loss	$ (2,999,000)	$ (6,010,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	111,000	99,000
Loss from disposal of property and equipment	1,000	--
Non cash expense related to employee stock options	49,000	--
Changes in operating assets and liabilities:		
Accounts receivable	1,075,000	(1,368,000)
Inventories	629,000	663,000
Prepaid expenses and other assets	332,000	1,093,000
Accounts payable and other accrued expenses	(742,000)	(1,011,000)
Accrued compensation and employee benefits	(633,000)	(408,000)
Accrued clinical trials expense	(30,000)	(871,000)
Accrued professional fees	91,000	(57,000)
Long-term liabilities	(544,000)	--
Deferred revenue	(268,000)	(269,000)
Net cash used in operating activities	(2,928,000)	(8,139,000)
Investing activities:		
Purchases of property and equipment	(42,000)	(49,000)
Purchases of marketable securities	(52,000)	(53,000)
Net cash used in investing activities	(94,000)	(102,000)
Financing activities:		
Proceeds from issuances of common stock, net of financing costs	1,083,000	160,000
Net cash provided by financing activities	1,083,000	160,000
Net decrease in cash and cash equivalents	(1,939,000)	(8,081,000)
Cash and cash equivalents, beginning of period	41,204,000	52,899,000
Cash and cash equivalents, end of period	$ 39,265,000	$ 44,818,000

See notes to condensed consolidated financial statements

SCICLONE PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Basis of Presentation

SciClone was reincorporated in the State of Delaware on July 18, 2003. The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles consistent with those applied in, and should be read in conjunction with, the audited financial statements for the year ended December 31, 2004 included in the Company's Form 10-K/A for the year ended December 31, 2004 as filed with the Securities and Exchange Commission. The interim financial information reflects all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented and are not necessarily indicative of results for subsequent interim periods or for the full year. The condensed consolidated balance sheet at December 31, 2004 is derived from the audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The Company has made a classification change within the short-term liabilities in the condensed consolidated balance sheet as of December 31, 2004 to conform to the current period presentation.

2. Significant Accounting Policies

Revenue Recognition

The Company recognizes revenue from product sales at the time of shipment. There are no significant customer acceptance requirements or post shipment obligations on the part of the Company. Sales to importing agents or distributors are recognized at time of shipment when title to the product is transferred to them, and they do not have contractual rights of return except under limited terms regarding product quality. However, the Company will replace products that have expired or are deemed to be damaged or defective when delivered. Payments by the importing agents and distributors are not contingent upon sale to the end user by the importing agents or distributors.

Contract revenue for research and development is recorded as earned based on the performance requirements of the contract. Nonrefundable contract fees for which no further performance obligations exist, and there is no continuing involvement by the Company, are recognized on the earlier of when the payments are received or when collection is assured.

Revenue associated with substantive performance milestones is recognized based on the achievement of the milestones, as defined in the respective agreements and provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the inception of the agreement, and (ii) there are no future performance obligations associated with the milestone payment.

Net Loss Per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding. Potentially dilutive common shares from convertible debt, stock options and warrants are excluded, as their effect is antidilutive.

The total number of shares excluded from the calculations of diluted net loss per share for outstanding convertible notes were 1,368,280 for the period ended June 30, 2005 and 2004, respectively. The total number of shares under outstanding options excluded from the calculation of diluted net loss per share was 7,487,092 for the period ended June 30, 2005 and 6,578,290 for the corresponding period in 2004. The total number of shares under outstanding warrants excluded from the calculations of diluted net loss per share was none for the period ended June 30, 2005 and 904,760 for the corresponding period in 2004.

Accounting For Stock-Based Compensation

On August 8, 2005 we publicly announced our results for the quarter ended June 30, 2005, including $398,000 of non-cash expense related to accounting for a stock-based performance option. Upon further review it was determined that the reported expense should not be recorded in the quarter ended June 30, 2005. Our results as reported in this Form

10-Q for the three and six-month periods ended June 30, 2005 represent our actual results for these periods, and differ from our announced results due to the corresponding decrease in expenses, net loss and net loss per share. A charge for the same stock-based performance option will be recorded in, and is properly attributable to, the quarter ended September 30, 2005. The amount of the charge will depend upon our stock price and will therefore differ from the charge we estimated in our announcement on August 8, 2005.

The Company accounts for its stock option and employee stock purchase plans under the provisions of Accounting Principles Board Opinion 25 ("APB 25") and related Interpretations. Accordingly, the Company does not generally recognize compensation expense in accounting for its employee stock purchase plans and its stock option plans for awards to employees and directors granted with exercise prices at fair market value.

Pro forma information regarding net loss per share is required by Statement of Financial Accounting Standards No. 123 "Accounting for Stock-Based Compensation" as amended by Statement of Financial Accounting Standards No. 148 "Accounting for Stock-Based Compensation-Transition and Disclosure" (collectively "SFAS 123") and has been determined as if the Company had accounted for its stock awards under the fair value method of the Statements. The fair value of the awards was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for the three-month and six-month periods ended June 30, 2005 and the corresponding periods in 2004:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Weighted-average fair value of stock options granted	$ 2.02	$ 3.15	1.98	$ 3.35
Risk-free interest rate	3.8%	2.3%	3.6%	2.3%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Volatility factor of the expected market price of our common stock	74.00%	85.00%	75.00%	88.00%
Weighted-average expected life of option (years)	4.00	4.00	4.00	4.00

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee and director stock awards have characteristics significantly different from those of traded options, and because changes in subjective input assumptions can materially affect the fair value estimate, in the Company's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its stock options and purchases through the employee stock purchase plan.

Our CEO was granted a target stock price award (see Footnote 10, CEO Employment Agreement) and, therefore, the grant date fair values related to each of the four vesting portions of this award have been calculated and the related expense included in the SFAS 123 pro forma expense disclosure over their derived service periods. As of June 30, 2005, approximately $33,000 is included in the SFAS 123 pro forma expense below related to this award.

The following table illustrates the Company's pro forma net loss and net loss per share, had compensation expense for the Company's option and employee purchase plans been determined based on the fair value at the grant date consistent with the provisions of SFAS 123:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net loss - as reported	$ (1,505,000)	$ (2,877,000)	$ (2,999,000)	$ (6,010,000)
Total stock-based employee compensation expense determined under the fair value based method for all awards	(807,000)	(1,011,000)	(1,494,000)	(1,870,000)
Net loss - pro forma	$ (2,312,000)	$ (3,888,000)	$ (4,493,000)	$ (7,880,000)
Basic and diluted net loss per share - as reported	$ (0.03)	$ (0.06)	$ (0.07)	$ (0.13)
Basic and diluted net loss per share - pro forma	$ (0.05)	$ (0.09)	$ (0.10)	$ (0.18)

The effects of applying SFAS 123 for pro forma disclosures are not likely to be representative of the effects on reported net loss for future years due to the different number of options granted each year.

Recent Accounting Pronouncement

In December 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R") which revises SFAS 123, and supersedes APB 25, and its related implementation guidance. Generally the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R requires share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. The amount of compensation cost will be measured based on the grant-date fair value of the instruments issued. Compensation cost will be recognized over the period that an employee or director provides service in exchange for the award. We expect to adopt SFAS 123R on January 1, 2006.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees and directors using APB 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee and director stock options and employee stock purchase plans. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our results of operations, although it will have no impact on our cash or overall financial position. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS 123R using the Black-Scholes option pricing model in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and net loss per share in the Accounting for Stock-Based Compensation section.

3. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes net unrealized gains and losses on our available-for-sale securities. For the three-month periods ended June 30, 2005 and 2004, the Company's total comprehensive loss amounted to $(1,497,000) and $(2,910,000), respectively. For the six-month periods ended June 30, 2005 and 2004, the Company's total comprehensive loss amounted to $(2,996,000) and $(5,987,000), respectively.

4. Available-For-Sale Securities

The following is a summary of available-for-sale securities at June 30, 2005 and December 31, 2004:

	Available-For Sale Securities		
	Amortized Cost	Gross Unrealized Gains	Estimated Fair Value
June 30, 2005:			
Certificates of deposit	$ 808,000	$ --	$ 808,000
U.S. government obligations	16,132,000	--	16,132,000
Short-term municipal securities	9,250,000	--	9,250,000
Corporate equity securities	51,000	41,000	92,000
	$ 26,241,000	$ 41,000	$ 26,282,000
December 31, 2004:			
Certificates of deposit	$ 805,000	$ --	$ 805,000
U.S. government obligations	22,843,000	--	22,843,000
Short-term municipal securities	9,200,000	--	9,200,000
Corporate equity securities	51,000	38,000	89,000
	$ 32,899,000	$ 38,000	$ 32,937,000

As of June 30, 2005, the available-for-sale securities are included as follows: $16,132,000 in cash and cash equivalents; $693,000 in restricted short-term investments and $9,457,000 in other short-term investments. As of December 31, 2004, the available-for-sale securities are included as follows: $22,843,000 in cash and cash equivalents; $700,000 in restricted short-term investments and $9,395,000 in other short-term investments. As of June 30, 2005 and December 31, 2004 all available-for sale securities excluding the short-term municipal securities had maturities of 12 months or less. The short-term municipals are auction rate securities which have long final maturities; however, they are highly rated, highly liquid and their interest rate is reset at auction every 30 days. The Company's interest rate risk associated with the auction rate securities is limited due to this interest rate reset mechanism.

5. Inventories

The following is a summary of inventories at June 30, 2005 and December 31, 2004:

	June 30, 2005	December 31, 2004
Raw materials	$ 1,144,000	$ 1,517,000
Work in progress	980,000	276,000
Finished goods	1,426,000	2,386,000
	$ 3,550,000	$ 4,179,000

6. Prepaid Expenses and Other Current Assets

The following is a summary of prepaid expenses and other current assets at June 30, 2005 and December 31, 2004:

	June 30, 2005	December 31, 2004
Prepaid insurance	$ 246,000	$ 694,000
Prepaid rent	102,000	102,000
Prepaid clinical trial expense	44,000	247,000
VAT receivable	300,000	142,000
Other prepaid expenses	457,000	293,000
	$ 1,149,000	$ 1,478,000

7. Intangible Assets

The following is a summary of intangible assets at June 30, 2005 and December 31, 2004:

	June 30, 2005	December 31, 2004
Intangible product rights	$ 2,456,000	$ 2,456,000
Accumulated amortization	(1,949,000)	(1,914,000)
	$ 507,000	$ 542,000

Acquired ZADAXIN product rights are being amortized on a straight-line basis beginning in September 1998. Amortization expenses for each of the three-month periods ended June 30, 2005 and 2004 was $17,500 and for each of the six-month periods ended June 30, 2005 and 2004 was $35,000. For the years ending December 31, 2005 through 2012, annual amortization expense is expected to be $70,000. Based upon the progress in the ZADAXIN clinical trials and the Company's actual experience of product sales, the Company assessed that the acquired product rights will be useful to the Company through 2012 when the European patent for the use of ZADAXIN in the treatment of hepatitis C expires. The Company's policy is to identify and record impairment losses on intangible product rights when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. There have been no impairment losses recorded to date.

8. Contract Revenue

In January 2002, the Company received $2,685,000 from its European partner, Sigma-Tau, under the terms of its collaborative agreement announced in late December 2001. This receipt has been recorded as deferred revenue and is being recognized as contract revenue over the course of the ZADAXIN hepatitis C U.S. clinical program and the period of sharing the clinical data from this program with Sigma-Tau, the substantive performance requirements under the contract.

9. Other Accrued Expenses

The following is a summary of other accrued expenses at June 30, 2005 and December 31, 2004:

	June 30, 2005	December 31, 2004
Accrued royalties	$ 400,000	$ 420,000
Accrued pre-clinical trial expenses	169,000	133,000
Accrued interest payable	52,000	52,000
Accrued sales and marketing expenses	510,000	492,000
Accrued manufacturing costs	472,000	--
Other	422,000	312,000
	$ 2,025,000	$ 1,409,000

10 **CEO Employment Agreement**

The Company entered into an employment agreement with its new CEO effective June 1, 2005. In accordance with the CEO employment agreement, the CEO's new hire bonus of $100,000 will be amortized over two years. In 2008, the Board of Directors is obligated to consider an award to the CEO of a special cash bonus of up to $300,000, based on the CEO's achievement of the previously agreed upon performance targets over the years 2005-2007. The Company will estimate the probable amount of this long-term incentive bonus on a quarterly basis in order to accrue the bonus over the related performance period. All expenses related to the CEO employment agreement are being recorded to general and administrative expenses in the accompanying statements of operations.

The employment agreement included the award of two options. The first option is to purchase 400,000 shares of the Company's common stock at $2.97 per share, the closing price on the Nasdaq National Market of a share of the Company's common stock on June 1, 2005. The option has a term of 10 years and, subject to the CEO's continued employment by the Company, will vest in annual installments on each of the first four anniversaries of June 1, 2005. The Company has not recognized any compensation expense related to this stock option as it was granted with an exercise price equal to the price of the Company's common stock on the date of grant.

The second option granted to the CEO is to purchase 400,000 shares of the Company's common stock at $2.97 per share, the closing price on the Nasdaq National Market of a share of the Company's common stock on June 1, 2005. This option has a term of 10 years and 25% of such second option will vest upon the Company's common stock trading after June 1, 2005 for at least 30 consecutive calendar days at or greater than a target closing stock price, as reported on the Nasdaq National Market, of (a) $4.50 on or before June 1, 2008, (b) $6.00 on or before June 1, 2009, (c) $8.00 on or before June 1, 2010, and (d) $10.00 on or before June 1, 2011, each price as adjusted for stock dividends, stock splits or similar changes in the Company's capital structure.

Under APB 25, the Company recognizes non-cash expense related to the stock price performance based option granted to our Chief Executive Officer on June 1, 2005, the date he commenced his employment. The terms of this option require the application of variable accounting, and in this case the related non-cash expense to be recognized is effected by the price level of trading activity in our stock. The Company recognizes non-cash expense when the vesting of a portion of the option is determined to be probable. At June 30, 2005, the vesting of a portion of the option was not probable and, therefore, no expense related to this option was recognized for the three-month period ended June 30, 2005. From June 30, 2005 to July 30, 2005 the market price of the Company's common stock increased from $4.49 to $7.20 per share. During this time period the market price of the Company's common stock price had closed above $4.50 for at least 30 consecutive calendar days thus triggering the vesting of 25% of the shares underlying the option. Therefore, the Company will recognize a $423,000 non-cash expense attributable to this vesting in the three-month period ended September 30, 2005. If additional portions of this option vest or are deemed probable of vesting by September 30, 2005, there would be additional and potentially significantly greater non-cash expense to be recorded in that period.

Under SFAS 123, the second option is considered a target stock price award and, therefore, the grant date fair values related to each of the four vesting portions of this award have been calculated and the related expense included in the SFAS 123 pro forma expense disclosure over the derived service periods for each of the four vesting portions of the award. The aggregate fair value of the award was estimated to be $691,000 at the date of grant using a Monte Carlo simulation option pricing model with the following assumptions, risk-free interest rate of 4.097%; dividend yield of 0%; volatility factor of 74% and expected life of 10 years. The fair values of the four vesting portions of the awards of $186,000, $173,000, $166,000 and $166,000 are being amortized over their related derived service periods which are 13, 21, 28, and 36 months, respectively. For the three months ended June 30, 2005, approximately $33,000 of such

expense is included in the SFAS 123 pro forma expense (see Footnote 2, Significant Accounting Policies, Accounting for Stock-Based Compensation).

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are based on our current expectations, estimates and projections about our business, industry, management's beliefs and certain assumptions made by us. Words such as "anticipate," "expect," "intend," "plan," "believe" or similar expressions are intended to identify forward-looking statements including those statements we make regarding our future financial results; anticipated product sales; the sufficiency of our resources to complete clinical trials and other new product development initiatives; the timing and outcome of clinical trials; the timing of completion of therapy and observation for our clinical trials; ZADAXIN's ability to complement existing therapies; prospects for ZADAXIN and our plans for its enhancement and commercialization; future size of the worldwide hepatitis C virus market; research and development and other expense levels; cash and other asset levels; and the allocation of financial resources to certain trials and programs. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Therefore, our actual results could differ materially and adversely from those expressed in any forward-looking statements as a result of various factors including, but not limited to, those described under the caption "Risk Factors" in this Quarterly Report on Form 10-Q. We undertake no obligation to revise or update publicly any forward-looking statements for any reason.

Overview

SciClone Pharmaceuticals, Inc. is a biopharmaceutical company engaged in the development and commercialization of therapeutics to treat life-threatening diseases. We and Sigma-Tau, our European marketing and development partner are currently evaluating our lead product, ZADAXIN, in several late stage clinical trials for the treatment of patients with the hepatitis C virus, or HCV, the hepatitis B virus, or HBV, and certain types of cancer. Our primary objective is to obtain regulatory approvals for ZADAXIN and optimize its commercial opportunities for the treatment of these indications in the major pharmaceutical markets of the United States, Europe and Japan. We believe the worldwide market for HCV therapies alone was approximately $3 billion in 2004 and could exceed $8 billion in 2012. Our two ongoing ZADAXIN phase 3 HCV clinical trials in the United States are designed to demonstrate the efficacy of ZADAXIN used in combination with pegylated interferon alpha for the treatment of HCV patients who have failed previous therapy, commonly referred to as non-responders. These clinical trials are scheduled to be completed by the end of 2005. The objective of these U.S. trials is to use the results, if positive, to achieve regulatory approval. In Europe, Sigma-Tau is conducting a phase 3 HCV non-responder trial evaluating ZADAXIN in combination with pegylated interferon alpha and ribavirin, now considered to be the current standard of care. The results of this triple therapy trial, if successful, as well as results from additional future clinical trials would be used to provide additional clinical data on ZADAXIN's use as an addition to the current treatment regimen for a majority of hepatitis C patients and to support regulatory and commercial prospects for ZADAXIN in a variety of clinical settings. ZADAXIN is also being evaluated in an ongoing phase 2 malignant melanoma clinical trial in Europe sponsored by Sigma-Tau, ongoing phase 2 proof-of-concept studies in the United States for the treatment of liver cancer, and an ongoing HBV clinical trial in Taiwan. ZADAXIN is approved for sale in more than 30 other countries primarily for the treatment of HBV. Our largest current market is in China where the sale of ZADAXIN is supported by our organization of approximately 100 medical representatives. We intend to leverage this significant marketing capability by in-licensing additional drug products that may be effectively and efficiently sold by our organization to the hospital-based pharmaceutical market in China. Our other proprietary drug development candidate is SCV-07, a potential therapeutic to treat viral and other infectious diseases. We commenced a phase 1 clinical trial in the United States for SCV-07 in August 2005.

Results of Operations

Total Revenues

Product sales were $6,851,000 and $13,512,000 for the three-month and six-month periods ended June 30, 2005, respectively, as compared to $5,613,000 and $11,027,000 for the corresponding periods in 2004. All product sales in each period were derived from sales of ZADAXIN. The increases in these periods were attributable to higher volumes of product sold as prices have remained stable between the 2004 and 2005 periods. Sales to customers in China for both the three-month and six-month periods ended June 30, 2005 accounted for approximately 91% of product sales as compared to 91% and 90% for the corresponding periods in 2004.

For the three-month period ended June 30, 2005, sales to three importing agents in China accounted for approximately 15%, 29% and 47% of our product sales, respectively. For the six-month period ended June 30, 2005, sales to three importing agents in China accounted for 16%, 24% and 51% of our product sales, respectively. The single largest customer in each of

these two periods was not the same importing agent. For the three-month period ended June 30, 2004, sales to one importing agent in China accounted for 91% of our product sales. However, for the six-month period ended June 30, 2004, the same importing agent in China accounted for only 65% of our product sales and another importing agent in China accounted for 25% of our product sales. We expect that the share of our product sales to China will vary among a small number of importing agents from quarter to quarter.

Contract revenue was $134,000 and $268,000 for the three-month and six-month periods ended June 30, 2005, respectively, as compared to $1,135,000 and $1,363,000 for each of the corresponding periods in 2004. Contract revenue in these 2004 periods included a $1,000,000 milestone payment from Sigma-Tau for completion of enrollment in our U.S. phase 3 hepatitis C trials. All of the other contract revenue in the 2004 and 2005 periods was recognized in connection with the $2,685,000 payment we received from Sigma-Tau in January 2002. This revenue is being recognized as contract revenue over the course of the ZADAXIN hepatitis C U.S. clinical program and the period of sharing the clinical data from this program with Sigma-Tau in accordance with the requirements under our contract with Sigma-Tau.

Cost of Product Sales and Gross Margin on Product Sales

Gross margin on product sales was 83% and 84% for the three-month and six-month periods ended June 30, 2005, respectively, as compared to 79% for both the three-month and six-month periods ended June 30, 2004. The prices of ZADAXIN sales were similar in the comparable periods, and the increase in gross margin percentage was primarily the result of lower product costs for product sold in the 2005 period. Much of this product had been produced by our former contract manufacturer in relatively higher volume production runs resulting in a relatively lower level of fixed cost absorption per unit. In addition, the cost of $324,000 and $105,000 of the product sold in the six-month and three-month periods ended June 30, 2005, respectively, had been previously written off in 2004 as a result of management's concerns at that time of its salability because this inventory was approaching its minimum shelf life accepted by our customers. We expect such factors to have no effect in the quarter ending September 30, 2005 and in subsequent quarters. The average unit cost of products sold in subsequent quarters in 2005 is expected to be higher than that for the three-month and six-month periods ended June 30, 2005. We expect cost of product sales, and gross margin on product sales, to vary from period to period, depending upon the sales levels and prices of ZADAXIN, the absorption of product-related fixed costs, and any charges associated with excess or expiring finished product inventory.

Research and Development Expenses

Research and development expenses were $3,479,000 and $6,960,000 for the three-month and six-month periods ended June 30, 2005, respectively, as compared to $5,145,000 and $9,076,000 for the corresponding periods in 2004. The decrease was primarily related to the U.S. phase 3 hepatitis C clinical trials, which are nearing completion by the end of 2005. The initiation and continuation of our current clinical development programs has had and will continue to have a significant effect on our research and development expenses. Although it is not possible to determine the total cost expected to be incurred for each clinical trial due to the uncertain nature of the clinical trial process, we estimate that our future costs through June 30, 2006 relating to our current U.S. phase 3 clinical trials will be approximately $3,400,000 and that our share of the future costs through 2007 of the current European HCV phase 3 clinical trial will be approximately $3,3,00,000. We estimate that our recently commenced phase 1 clinical trial in the United States for SCV-07 will cost approximately $1,000,000 through early 2006. In general, we expect research and development expenses to vary substantially from quarter to quarter as we pursue our strategy of initiating additional preclinical and clinical trials and testing, acquiring product rights, and expanding regulatory activities.

Sales and Marketing Expenses

Sales and marketing expenses were $2,432,000 and $4,760,000 for the three-month and six-month periods ended June 30, 2005, respectively, as compared to $2,148,000 and $4,591,000 for the corresponding periods in 2004. The higher levels of sales and marketing expenses in these 2005 periods were due to increased conferences and related expenses associated with the expansion of our marketing efforts and payroll related expenses of $223,000 and $199,000 in the three-month and six-month periods ended June 30, 2005, respectively that led to higher levels of product sales. We expect sales and marketing expenses to vary in the next several quarters and to increase in the next several years if we are successful in our efforts to expand our commercialization and marketing efforts.

General and Administrative Expenses

General and administrative expenses were $1,588,000 and $3,208,000 for the three-month and six-month periods ended June 30, 2005, respectively, as compared to $1,156,000 and $2,449,000 for the corresponding periods in 2004. The increases in general and administrative expenses were primarily attributable to increased legal expense of $98,000 and $285,000 in the

three-month and six-month periods ended June 30, 2005, respectively, and higher expenses incurred with Sarbanes Oxley compliance efforts of $82,000 and $301,000 in the three-month and six-month periods ended June 30, 2005, respectively. In the three-month period ended September 30, 2005, the Company will recognize $423,000 of non-cash stock-related compensation expense attributable to the vesting of the CEO's target stock price option. If additional portions of the CEO's target stock price option vest or are deemed probable of vesting by September 30, 2005, there would be additional and potentially significantly greater non-cash expense to be recorded in that period. In the near term, we expect general and administrative expenses to vary from quarter to quarter as we increase our general and administrative activities to support increased securities regulation requirements and legal and regulatory activities and recognize non-cash employee stock-based compensation expense related to the vesting of the CEO's target stock price award if our stock price maintains 30 consecutive calendar days at or greater than a target closing price.

Interest and Investment Income and Expense

Interest and investment income was approximately $286,000 and $519,000 for the three-month and six-month periods ended June 30, 2005, respectively, as compared to $112,000 and $228,000 for the corresponding periods in 2004. The increases were primarily due to cash balances earning higher interest rates in the 2005 periods. Interest expense of $91,000 in each of the respective three-month periods ended June 30, 2005 and 2004, and of $181,000 in each of the respective six-month periods ended June 30, 2005 and 2004, relates to the $5,600,000 of convertible notes payable outstanding throughout these periods.

Liquidity and Capital Resources

On June 30, 2005 and December 31, 2004, we had $49,415,000 and $51,299,000, respectively, in cash, cash equivalents and short-term investments including $693,000 and $700,000, respectively, of restricted short-term investments. We currently estimate cash, cash equivalents and short-term investments at December 31, 2005 will be lower than the balance at June 30, 2005. The expected decrease in this balance is attributable to further expected net losses and the assumption that the outstanding $4,000,000 note, convertible into our common stock at a price of $9.8133 per share, due December 2005 will be repaid rather than converted. The short-term investments consist primarily of highly liquid marketable securities. Our restricted short-term investments relate to two letters of credit each secured by a certificate of deposit. On June 30, 2005, the letters of credit totaled $693,000 and were comprised of $633,000 under our lease agreement and $60,000 to facilitate our value added tax filings in Europe.

Net cash used in operating activities amounted to $2,928,000 for the six-month period ended June 30, 2005 as compared to net cash used in operating activities in the amount of $8,139,000 in the corresponding period in 2004. The change in the 2005 period was primarily due to a lower net loss incurred, as well as a decrease in accounts receivable.

Net cash used by us in investing activities amounted to $94,000 for the six-month period ended June 30, 2005, as compared to net cash used by us in investing activities in the amount of $102,000 for the corresponding period in 2004.

Net cash provided by financing activities amounted to $1,083,000 for the six-month period ended June 30, 2005, of which $1,006,000 was related to the exercising of outstanding options under our employee stock option plans, and $77,000 was from the issuance of common stock under our employee stock purchase plan. For the six-month period ended June 30, 2004, net cash provided by financing activities amounted to $160,000, all of which was generated from the issuance of common stock under our employee stock purchase plan.

The outstanding $1,600,000 note will mature in March 2006 and is convertible into 276,530 shares of common stock at a fixed conversion price of $5.7860 per share. The note holder also has the right to purchase, at any time up to the note's maturity date, approximately $2,400,000 of convertible notes due March 2006. If issued, the notes will bear no interest (zero coupon) and will be convertible into 276,530 shares of common stock at a fixed conversion price of $8.5532 per share. The Company may elect in lieu of delivering convertible notes to deliver the respective number of shares of common stock.

We intend to give priority use of our financial resources to ZADAXIN clinical programs. We estimate that our future costs through June 30, 2006 relating to our current U.S. phase 3 clinical trials will be approximately $3,800,000 and that our share of the future costs through 2007 of the current European HCV phase 3 clinical trial will be approximately $2,800,000. We estimate that our recently commenced phase 1 clinical trial in the United States for SCV-07 will cost approximately $1,000,000 through early 2006. We believe our existing capital resources and funds from product sales are sufficient to complete these trials and to proceed with the clinical development of SCV-07 and to initiate possible additional clinical trials for ZADAXIN in the United States, Europe or in Japan. If our HCV clinical trials are successful and we receive FDA approval by the U.S. Food and Drug Administration (FDA) we believe that our capital resources are sufficient to begin commercialization of ZADAXIN in the United States. We may undertake additional studies to obtain data to allow us to

optimize the commercial success of ZADAXIN in a variety of clinical settings. In particular, we believe that supporting the use of ZADAXIN as an addition to the current treatment for the majority of hepatitis C patients may require additional trials. However, we cannot assure you that our capital resources will be sufficient, or that sales of ZADAXIN, if approved in the United States, will result in profitable operations. If we need to raise additional financing, the unavailability or the inopportune timing of any financing could prevent or delay our long-term product development and commercialization programs, either of which would severely hurt our business. The need, timing and amount of any such financing would depend upon numerous factors, including the level of ZADAXIN sales, the timing and amount of manufacturing costs related to ZADAXIN, the availability of complementary products, technologies and businesses, the initiation and continuation of preclinical and clinical trials and testing, the timing of regulatory approvals, developments in relationships with existing or future collaborative parties and the status of competitive products.

Contractual Obligations

There were no material changes in the six-month period ended June 30, 2005 to our contractual obligations as disclosed in our Form 10-K/A for the year ended December 31, 2004.

Off-Balance Sheet Arrangements

There were no off-balance sheet arrangements in the six-month period ended June 30, 2005.

Recent Accounting Pronouncement

In December 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"). SFAS 123R requires share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. The amount of compensation cost will be measured based on the grant-date fair value of the instruments issued. Compensation cost will be recognized over the period that an employee or director provides service in exchange for the award. We expect to adopt SFAS 123R on January 1, 2006.

As permitted by Statement of Financial Accounting Standards (SFAS) 123, the Company currently accounts for share-based payments to employees and directors using Accounting Principles Board Opinion 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee and director stock options and employee stock purchase plans. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our results of operations, although it will have no impact on our cash or overall financial position. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS 123R using the Black-Scholes option pricing model in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and net loss per share in the Accounting for Stock-Based Compensation section of Note 2 of our condensed consolidated financial statements.

Recent Developments

We and Schering Plough K.K. (SPKK), a pharmaceutical company in Japan, have been involved in discussions regarding our concerns about the quality of the work that SPKK performed on the clinical studies in Japan for ZADAXIN up until 2001, and the effect that SPKK's work would have on any new drug application in Japan for ZADAXIN. These discussions included a meeting between SPKK's CEO and our management in July 2005. SPKK and we continue to investigate and discuss the issues involved, and how this matter should be fairly resolved. We are working closely with our counsel in the United States and Japan on this matter. Should discussions with SPKK not conclude to our satisfaction, we will be taking legal action against SPKK.

Information received from SPKK in the past few weeks has, in conjunction with our investigative efforts, led us to conclude that the studies in Japan cannot, at this time, be presented to Japanese regulatory authorities to support ZADAXIN in the treatment of Hepatitis B, on either a preliminary review basis or as part of an actual new drug application. This conclusion is based on the failure of SPKK to conduct certain audits and generate certain reports during the pre-2001 studies that it managed, and our conclusion that such documentation probably cannot be created at this time. The conclusion that we cannot move forward with Japanese authorities at this time is not based on the substantive results of the Japan trials, which showed ZADAXIN to have competitive efficacy and safety in the treatment of hepatitis.

Given this recent conclusion, our management, in conjunction with the Board of Directors, is now determining the steps it will take to move ZADAXIN forward in Japan including a revised development plan. However, it is unlikely that we will be able to present a new drug application for ZADAXIN in Japan for some years.

Risk Factors

You should carefully consider the risks described below, in addition to the other information in this report on Form 10-Q and our report on Form 10-K for the year ended December 31, 2004, before making an investment decision. Each of these risk factors could adversely affect our business, financial condition, and operating results as well as adversely affect the value of an investment in our common stock.

If we are unable to commercialize ZADAXIN in various markets for multiple indications, particularly in the United States for the treatment of HCV, our business will be harmed.

Our ability to achieve and sustain operating profitability depends in large part on our ability to commence, execute and complete clinical programs and obtain additional regulatory approvals for ZADAXIN and other drug candidates, particularly in the United States, Europe and Japan We are also dependent on our ability to increase ZADAXIN sales in existing markets and launch ZADAXIN in new markets. In particular, our ability to achieve and sustain profitability will depend in large part on our ability to commercialize ZADAXIN for the treatment of HCV in the United States. Our two U.S. phase 3 HCV clinical trials have been designed to show that the combination of ZADAXIN and pegylated interferon alpha adds a significant clinical benefit when compared to the use of pegylated interferon alpha alone in non-responders, and if approved by the FDA, the approval will be for the use of ZADAXIN with pegylated interferon alpha for the treatment of non-responders to previous HCV therapy. The current standard of care for HCV therapy is the combination of pegylated interferon alpha with ribavirin. This combination is not approved by the FDA or the European Agency for the Evaluation of Medicinal Products (EMEA) for the treatment of non-responders, however, in clinical practice pegylated interferon alpha with ribavirin is widely used for the treatment of both treatment naïve and non-responder HCV patients. If approved, our commercial prospects may be limited by the labeling for use only in non-responders and by the perceived comparative efficacy of the combination of ZADAXIN and pegylated interferon alpha against that of the current standard of care. The European HCV phase 3 clinical trial being conducted by Sigma-Tau has been designed to compare the efficacy of the triple combination of ZADAXIN, pegylated interferon alpha and ribavirin with the current standard of care. The final results of the European trial will not be known before the end of 2007. We believe that this trial, as well as possible additional trials, could be important to support the use of ZADAXIN as an addition to the current standard of care and address a broader HCV patient population. We cannot assure you that we will achieve significant levels of sales or that we will receive approval for ZADAXIN for the treatment of HCV in the United States or for the treatment of HCV or other indications in other countries. If we are unable to do so, our business will be harmed.

If we do not obtain regulatory approval for ZADAXIN for the intended indications that we are evaluating, our revenues will be limited and we will not become profitable.

Our ability to execute on our business strategy is largely dependent on our ability to obtain regulatory approval for the use of ZADAXIN, particularly for the treatment of HCV in the United States and in Europe. If our current HCV phase 3 clinical trials in the United States yield favorable results, we intend to submit an application for marketing approval of ZADAXIN for the treatment of HCV in the United States and through our partner, Sigma-Tau, for the treatment of HCV in Europe. The regulatory approval processes in the United States and Europe are demanding and typically require 12 months or more in the United States and 18 months or more in Europe from the date of submission of a New Drug Application (NDA). We have committed significant resources, including capital and time, to develop ZADAXIN, particularly for HCV in the United States, with the goal of obtaining such approvals. If we do not obtain these approvals, we will be unable to achieve any substantial increase in our revenue from ZADAXIN and our ZADAXIN sales in other jurisdictions could decline.

All new drugs, including our products, which have been developed or are under development, are subject to extensive and rigorous regulation by the FDA and comparable agencies in state and local jurisdictions and in foreign countries. These regulations govern, among other things, the development, testing, manufacturing, labeling, storage, pre-market approval, importation, advertising, promotion, sale and distribution of our products. These regulations may change from time to time and new regulations may be adopted.

Obtaining regulatory approval in developing countries also is time-consuming and expensive. In some countries where we are contemplating marketing and selling ZADAXIN, the regulatory approval process often relies on prior approvals obtained in the United States or in Europe. Without such prior approvals, our ability to obtain regulatory approvals for ZADAXIN in these countries may be delayed or prevented. In addition, to secure these regulatory approvals, we will need, among other things, to demonstrate favorable results from additional clinical trials of ZADAXIN. Even if we are able to complete the clinical trials we have sponsored or are planning in a timely or cost-effective manner, these trials may not fulfill the applicable regulatory approval criteria, in which case we will not be able to obtain regulatory approval in these countries, and we have experienced difficulties in preparing for regulatory approval in Japan. We cannot assure you that we will ultimately obtain

regulatory approvals in our targeted countries in a timely and cost-effective manner or at all. If we fail to obtain the required regulatory approvals to develop, market and sell our products in countries where we currently do not have such rights, our revenues will be limited.

Satisfaction of government regulations may take several years and the time needed to satisfy them varies substantially based on the type, complexity and novelty of the pharmaceutical product. As a result, government regulation may cause us to delay the introduction of, or prevent us from marketing, our existing or potential products for a considerable period of time and impose costly procedures upon our activities. Even if we obtain regulatory approval for our products, such approval may impose limitations on the indicated uses for which our products may be marketed. Unsatisfactory data resulting from clinical trials may also adversely affect our ability to market and sell ZADAXIN in markets where it is approved for sale.

If the results of our clinical trials are not favorable, we will be unable to obtain regulatory approval for the intended indications we are evaluating.

To obtain regulatory approvals, we must, among other requirements, complete carefully controlled and well-designed clinical trials demonstrating that a particular drug is safe and effective for the applicable disease. We cannot depend on data from prior trial results to predict or demonstrate that our potential drug products are safe and efficacious under regulatory guidelines to qualify for commercial sale. We cannot assure you, nor can you rely on our previous clinical trial results to predict, that our ongoing or future clinical trials will yield favorable results. Adverse or inconclusive clinical results would prevent us from filing for regulatory approval of ZADAXIN (thymosin alpha 1) for the indications that we are evaluating, and our current programs in those areas would fail. In the past, Alpha 1 Biomedical, from which we acquired certain rights to thymosin alpha 1, conducted a phase 3 clinical trial of thymosin alpha 1 as a therapy for HBV that did not produce statistically significant results and Alpha 1 Biomedical did not submit an NDA to the FDA.

We are currently conducting phase 3 clinical trials based on the use of ZADAXIN in combination with pegylated interferon alpha for the treatment of HCV patients who did not previously respond to treatment. We cannot assure you that these phase 3 clinical trials will yield sufficient or adequate data to demonstrate appropriate safety and efficacy under FDA guidelines. Any failure to obtain sufficient or adequate data could delay or prevent us from securing FDA approval.

Our two phase 3 HCV clinical trials in the United States have been designed to show that the combination of ZADAXIN and pegylated interferon alpha adds a significant clinical benefit when compared to the use of pegylated interferon alpha alone in non-responders. We cannot assure you that the results of this combination therapy will be favorable, or that the independent use of pegylated interferon alpha will not perform better than anticipated, either of which could reduce the chances that an NDA will be approved or that we will submit an NDA based on such results. The protocols of our two U.S. phase 3 clinical trials are essentially identical except that one trial includes HCV patients without evidence of cirrhosis and the other trial includes cirrhotic HCV patients. HCV patients whose disease has progressed to cirrhosis have been shown to be very difficult to treat with the current standard of care. Even if our trial with non-cirrhotic patients yields favorable results, our trial with cirrhotic patients may not be successful and we may be unable to obtain regulatory approval. If the combination therapy of ZADAXIN and pegylated interferon alpha causes significant adverse side effects beyond those caused by pegylated interferon alpha alone, the ongoing treatment in our clinical trials could be halted or delayed, or the regulatory agencies may reject an NDA due to safety issues. If any of the foregoing occurs, our efforts to market and sell ZADAXIN in the United States and Europe will be significantly impaired, our business will suffer and the price of our stock may decline.

In addition, ZADAXIN is being evaluated in other clinical trials. In particular, Sigma-Tau is conducting a phase 2 malignant melanoma trial using ZADAXIN. Sigma-Tau expects to release preliminary data by the end of 2005, however, we cannot ensure that these data will be released at this time. Since these data are preliminary in nature, they may not be indicative of final data.

Higher than anticipated patient drop out rates in our clinical trials could make it more difficult to obtain regulatory approval.

Each of our two current phase 3 HCV clinical trials in the United States enrolled more than the planned number of 500 patients, one trial treating patients with no liver damage and the other trial treating patients with mild cirrhosis of the liver. The trials require patient treatment for 48 weeks and a follow-up observation period for an additional 24 weeks. Patient dropouts were expected, but have been higher than anticipated. A patient who drops out at any point in the 72 weeks of the trial is considered a “failure to respond” in results of the clinical trial. We do not expect that dropouts will prevent us from completing our trials. However, in general, the fewer patients who complete each trial, the higher the positive response rate for the group of remaining ZADAXIN treated patients in such trial needs to be in order to demonstrate statistical significance.

Therefore, a higher than anticipated dropout rate lowers our chances of proving statistical significance which could adversely effect our preparation of an NDA.

We cannot predict the safety profile of the use of ZADAXIN when used in combination with other drugs.

Many of our trials involve the use of ZADAXIN in combination with other drugs. Some of these drugs, particularly pegylated interferon alpha and ribavirin are known to cause adverse patient reactions. Even if ZADAXIN does not produce adverse side effects when used alone, we cannot predict how it will work with other drugs, including causing possible adverse side effects not directly attributable to the other drugs that could compromise the safety profile of ZADAXIN when used in certain combination therapies.

If we lose key personnel or are unable to attract and retain additional, highly skilled personnel required for the expansion of our activities, our business will suffer.

We are highly dependent upon our ability to attract and retain qualified personnel because of the specialized, scientific and worldwide nature of our business. Following the departure of our Chief Executive Officer on July 14, 2004, we established an Office of the President, and believe that the Company continued to function effectively under the Office of the President. Our new President and Chief Executive Officer, Dr. Ira Lawrence, began his service to the Company on June 1, 2005. However, we may be affected adversely by any future changes in our key management personnel. There is intense competition for qualified management, scientific and technical personnel in the pharmaceutical industry, and we may not be able to attract and retain the qualified personnel we need to grow and develop our business globally. In addition, we assign numerous key responsibilities to a limited number of individuals, and we would experience difficulty in finding immediate replacements for any of them. If we were unable to attract and retain qualified personnel as needed or promptly replace those employees who are critical to our product development and commercialization, the development and commercialization of our products would be adversely affected. At this time, we do not maintain "key person" life insurance on any of our personnel.

Our revenue is dependent on the sale of ZADAXIN in foreign countries, particularly China, and if we experience difficulties in our foreign sales efforts, our financial condition will be harmed.

Our product revenue in the near term is highly dependent on the sale of ZADAXIN in foreign countries. If we experience difficulties in our foreign sales efforts, our business will suffer and our financial condition will be harmed. Substantially all of our ZADAXIN sales are to customers in China. Sales of ZADAXIN in China may be limited due to the low average personal income, lack of patient cost reimbursement, poorly developed infrastructure and existing and potential competition from other products, including generics. In China, ZADAXIN is approved only for the treatment of HBV and as a vaccine adjuvant. We face competition from certain large, global pharmaceutical companies who are aggressively marketing competing products for the treatment of HBV and other indications where ZADAXIN is used on an off-label basis. In addition, several local companies have introduced lower priced locally manufactured generic thymosin which is a competitive product. We expect such competition to continue and there could be a negative impact on the price and the volume of ZADAXIN sold in China, which would harm our business. Our efforts to in-license other pharmaceutical products for marketing in China and other markets may be unsuccessful or may not have a meaningful effect on our dependence on ZADAXIN sales in those markets.

Our ZADAXIN sales and operations in other parts of Asia, as well as in Latin America and the Middle East, are subject to a number of risks, including difficulties and delays in obtaining registrations, permits, pricing approvals and reimbursement and unexpected changes in regulatory requirements. We are also subject to the laws and regulations of other countries regarding the marketing, sale and distribution of our products in those countries where approvals have been obtained. We experience other issues with managing foreign sales operations including long payment cycles, difficulties in accounts receivable collection and, especially from significant customers, fluctuations in the timing and amount of orders. Operations in foreign countries also expose us to risks relating to difficulties in enforcing our proprietary rights, currency fluctuations and adverse or deteriorating economic conditions. If we experience problems with obtaining registrations, complying with reimbursement rules or compliance with other laws, or if we experience difficulties in payments or intellectual property matters in foreign jurisdictions, our results could be adversely affected.

We do not have product sales in the United States, Europe or Japan with which to offset any decrease in our revenue from ZADAXIN sales in Asia, Latin America and the Middle East, and sales outside of China have not been substantial to date. In addition, some countries in these regions, including China, regulate pharmaceutical prices and pharmaceutical importation. These regulations may reduce prices for ZADAXIN to levels significantly below those that would prevail in an unregulated market, limit the volume of product which may be imported and sold or place high import duties on the product, any of which may limit the growth of our revenues or cause them to decline.

Because of China's tiered method of importing and distributing finished pharmaceutical products, our quarterly results may vary substantially from one period to the next.

China uses a tiered method to import and distribute finished pharmaceutical products. At each port of entry, and prior to moving the product forward to the distributors, government-licensed importing agents must process and evaluate each shipment to determine whether such shipment satisfies China's quality assurance requirements. In order to efficiently manage this process, the importing agents typically place large, and therefore relatively few, orders within any six month period. Therefore, our sales to an importing agent can vary substantially from quarter to quarter depending on the size and timing of the orders, which has in the past and may in the future cause our quarterly results to fluctuate. We rely on four to six importers, in any given quarter, to supply substantially all of our product in China. Because we use a small number of importing agents in China, our receivables from any one importing agent are material, and if we were unable to collect receivables from any importer, our business and cash-flow would be adversely affected.

Our sales of ZADAXIN may fluctuate due to seasonality of product orders and sales in any quarter may not be indicative of future sales.

Our sales for the quarter ended June 30, 2003 were greatly affected by the demand in China for ZADAXIN in connection with the treatment of SARS. To date, SARS has not re-emerged, like influenza, as a seasonal public health problem. However, if SARS or a similar epidemic were to emerge, it is not possible to predict what effect, if any, this would have on future sales of ZADAXIN. Although we do not market ZADAXIN for use in treating such epidemic diseases, if ZADAXIN is purchased in connection with future outbreaks of seasonal viral contagions, product sales could become more concentrated in certain quarters of the calendar year, quarterly sales levels could fluctuate and sales in any quarter may not be indicative of sales in future periods.

If we fail to protect our products, technologies and trade secrets, we may not be able to successfully use, manufacture, market or sell our products, or we may fail to advance or maintain our competitive position.

Our success depends significantly on our ability to obtain and maintain meaningful patent protection for our products and technologies and to preserve our trade secrets. Our pending patent applications may not result in the issuance of patents in the future. Our patents or patent applications may not have priority over others' applications. Our existing patents and additional patents that may be issued, if any, may not provide a competitive advantage to us or may be invalidated or circumvented by our competitors. Others may independently develop similar products or design around patents issued or licensed to us. Patents issued to, or patent applications filed by, other companies could harm our ability to use, manufacture, market or sell our products or maintain our competitive position with respect to our products. Although many of our patents relating to ZADAXIN have expired, including composition of matter patents, we have rights to other patents and patent applications relating to ZADAXIN and ZADAXIN analogues, including method of use patents with respect to the use of ZADAXIN for certain indications. If other parties develop generic forms of ZADAXIN for other indications, including conducting clinical trials for such indications, our patents and other rights might not be sufficient to prohibit them from marketing and selling such generic forms of ZADAXIN. If other parties develop analogues or derivatives of ZADAXIN, our patents and other rights might not be sufficient to prohibit them from marketing these analogues or derivatives.

Pharmaceutical products are either not patentable or have only recently become patentable in some of the countries in which we market or may market ZADAXIN. We do not have patent protection for ZADAXIN in China, our largest market. Other companies market generic thymosin alpha 1 in China, sometimes in violation of our trademark or other rights which we defend by informing physicians and hospitals of the practice as well as through the limited legal recourse. Past enforcement of intellectual property rights in many of these countries, including China in particular, has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

If we are involved in intellectual property claims and litigation, the proceedings may divert our resources and subject us to significant liability for damages, substantial litigation expense and the loss of our proprietary rights.

Our commercial success depends in part on us not infringing valid, enforceable patents or proprietary rights of third parties, and not breaching any licenses that may relate to our technologies and products. We are aware of a third-party patent that may relate to our products and may cover a method of action used by ZADAXIN. We cannot assure you that our mechanism of action does not infringe on their claim. In addition, we may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our potential products. For example, U.S. patent applications may be kept confidential for 12 or more months while pending in the Patent and Trademark Office, and patent applications filed in

foreign countries are often first published six months or more after filing. It is possible that we may unintentionally infringe these patents or other patents or proprietary rights of third parties. We may in the future receive notices claiming infringement from third parties as well as invitations to take licenses under third-party patents. Any legal action against us or our collaborative partners claiming damages and seeking to enjoin commercial activities relating to our products and processes affected by third-party rights may require us or our collaborative partners to obtain licenses in order to continue to manufacture or market the affected products and processes. Our efforts to defend against any of these claims, regardless of merit, would require us to devote resources and attention that could have been directed to our operations and growth plans. In addition, these actions may subject us to potential liability for damages. We or our collaborative partners may not prevail in a patent action and any license required under a patent may not be made available on commercially acceptable terms, or at all. Any conflicts resulting from the patent rights of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection.

If other companies obtain patents with conflicting claims, we may be required to obtain licenses to those patents or develop or obtain alternative technology to manufacture or market the affected products and processes. We may not be able to obtain any such licenses on acceptable terms or at all. Any failure to obtain such licenses could delay or prevent us from pursuing the development or commercialization of our potential products. Our efforts to defend against any of these claims would require us to devote resources and attention that could have been directed to our operations and growth plans.

We may need to initiate litigation, which could be time-consuming and expensive, to enforce our proprietary rights or to determine the scope and validity of others' rights. If litigation results, a court may find our patents or those of our licensors invalid or may find that we have infringed on a competitor's rights. If any of our competitors have filed patent applications in the United States which claim technology we also have invented, the Patent and Trademark Office may require us to participate in expensive interference proceedings to determine who has the right to a patent for the technology. These actions may subject us to potential liability for damages. We or our collaborative partners may not prevail in a patent action and any license required under a patent may not be made available on commercially acceptable terms, or at all.

We rely on third parties to supply our clinical trial and commercial products. Deficiencies in their work could delay or harm one or more important areas of our business including our sales, clinical trials or the regulatory approval process.

We rely on third parties, who are subject to regulatory oversight, to supply our clinical and commercial products. We have been in the process of registering a new manufacturer of ZADAXIN and if we encounter problems with this process of validation, our sales or our clinical trials could be adversely affected. If sales of ZADAXIN were to increase dramatically, our third-party suppliers may not be able to supply ZADAXIN quickly enough, which could limit our ability to satisfy increased demand or could adversely affect the ability of these suppliers to provide products for our clinical trials. If unanticipated deficiencies in these suppliers occur, we could experience delays in our ability to assemble a timely and acceptable NDA. Roche is our exclusive supplier of pegylated interferon alpha for our current U.S. phase 3 HCV clinical trials. Any recall of the manufacturing lots of the pegylated interferon alpha used in our clinical trials could detract from the integrity of the trial data, in which case, our ability to complete the clinical trials in the United States and to market and sell ZADAXIN worldwide will be delayed or impaired, our business will suffer and the price of our stock may decline.

If we are not able to establish and maintain adequate manufacturing relationships, the development and sale of our products could be impaired.

To be successful, our products must be manufactured in commercial quantities, in compliance with stringent regulatory requirements and at an acceptable cost. Typically we have at any time only one supplier for each phase of manufacturing of our product. Manufacturing interruptions or failure to comply with regulatory requirements could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our products, including sales of ZADAXIN in approved markets, and impair our competitive position. Any of these developments would harm our business.

We are in the process of registering a new supplier for ZADAXIN with regulatory agencies in markets where ZADAXIN is approved for sale, and we have received such registration in China. This process, quality assurance and other steps could cause delays or interruptions of supply in certain other markets. In some countries, a manufacturing change may require additional regulatory approvals which may delay ZADAXIN marketing approvals in new markets. In addition, manufacturing, supply and quality control problems may arise as we, either alone or with subcontractors, attempt to scale-up our manufacturing procedures. We may not be able to scale-up in a timely manner or at a commercially reasonable cost, either of which could cause delays or pose a threat to the ultimate commercialization of our products and harm our business.

We may not be able to successfully develop or commercialize our products. We may consider strategic alliances with other companies in efforts to broaden our product development pipeline.

While we have limited sales of ZADAXIN in certain markets, we do not yet have regulatory approval for ZADAXIN for our principal target markets, and, in this respect, ZADAXIN is still being developed. Our other potential products are in earlier stages of development than ZADAXIN. We may consider and undertake various strategies to expand our portfolio of potential products, including acquiring product candidate rights through licenses or other relationships, or through other strategic relationships including acquisitions of other companies that may have proprietary rights to other development candidates or the capability to discover new drug candidates. Such transactions could require a substantial amount of our financial resources, or, if equity is involved, may result in substantial dilution to current stockholders. Strategic transactions also require substantial management time and effort and are subject to various risks that could adversely affect us or our financial results.

To fully develop our products, we will need to commit substantial resources to extensive research, development, pre-clinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to the potential products being ready for sale. We cannot assure that our efforts will produce commercially viable products. We face significant technological risks inherent in developing these products. We may also abandon some or all of our proposed products before they become commercially viable. If any of our products, even if developed and approved, cannot be successfully commercialized in a timely manner, our business will be harmed and the price of our stock may decline.

We have not yet sold any product other than ZADAXIN and our sales have been primarily in a single country, China. Our future revenue growth depends on increased market acceptance and commercialization of ZADAXIN in additional countries, particularly in the United States, Europe and Japan. If we fail to successfully market ZADAXIN, or if we cannot commercialize this drug in the United States and other additional markets, our revenue and operating results will be limited. If unexpected and serious adverse events are reported, or if expected efficacy results are not achieved, it would have a material adverse effect on our business. Our future revenue will also depend in part on our ability to develop other commercially viable and accepted products. Market acceptance of our products will depend on many factors, including our ability to convince prospective customers to use our products as an alternative to other treatments and therapies and to convince prospective strategic partners to market our products effectively and to manufacture our products in sufficient quantities with acceptable quality and at an acceptable cost. In addition, doctors must opt to use treatments involving our products. If doctors elect to use a different course of treatment, demand for our drug products would be reduced. Failure to do any of the above will lead to an unfavorable outcome on the results of our operations.

We rely on third-party clinical investigators to conduct our clinical trials and, as a result, we may encounter delays outside our control.

We have limited experience in conducting and managing clinical trials and we rely, in part, on third parties, particularly clinical research organizations and our development partners, to assist us in managing and monitoring clinical trials. Our reliance on these third parties may result in delays in completing, or failure to complete, these clinical trials if third parties fail to fulfill their obligations to us.

We may need to obtain additional capital to support our long-term product development and commercialization programs.

We believe our existing resources will be sufficient to complete our current U.S. phase 3 clinical trials and, if the trials are successful and we receive FDA approval, to begin commercialization of ZADAXIN in the United States. However, we cannot assure that such funds will be sufficient, or that sales of ZADAXIN, if approved in the United States, will result in profitable operations. In addition, we intend to develop other products and we may need additional funds in the future to support such development and to support future growth and achieve profitability. If we need to raise additional funds in the future and such funds are not available on reasonable terms, if at all, our commercialization efforts may be impeded, our revenues may be limited and our operating results may suffer.

We have a history of operating losses and an accumulated deficit. We expect to continue to incur losses in the near term and may never achieve profitability.

We have experienced significant operating losses since our inception, and as of June 30, 2005, we had an accumulated deficit of approximately $155 million. We expect our operating expenses to increase over the next several years as we plan to dedicate substantially all of our resources to expanding our development, testing and marketing capabilities, particularly in the United States, and these losses may increase if we cannot increase or sustain revenue. As a result, we may never achieve profitability.

We have limited sales, marketing and distribution capabilities, which may adversely affect our ability to successfully commercialize our products.

We currently have limited sales, marketing and distribution capabilities, and we anticipate that we may be relying on third-party collaborators to sell, market and distribute our products for the foreseeable future. If our arrangements with these third parties are not successful, or if we are unable to enter into additional third-party arrangements, we may need to substantially expand our sales, marketing and distribution force. Our efforts to expand may not succeed, or we may lack sufficient resources to expand in a timely manner, either of which will harm our future operating results. Moreover, if we are able to further expand our sales, marketing and distribution capabilities, we will begin competing with other companies that have experienced and well-funded operations. If we cannot successfully compete with these larger companies, our revenues may not grow and our business may suffer.

Commercialization of some of our products depends on collaborations with others. If our collaborators are not successful, or if we are unable to find future collaborators, we may not be able to properly develop and commercialize our products.

We depend in part on our distributors and business partners to develop or promote our drugs, and if they are not successful in their efforts or fail to do so, our business will suffer. For example, Sigma-Tau is responsible for the development and marketing of ZADAXIN in most of Europe. We generally do not have control over the amount and timing of resources that our business partners devote to ZADAXIN, and they have not always performed as or when expected. If they do not perform their obligations as we expect, particularly obligations regarding clinical trials, our development expenses would increase and the development or sale of our products could be limited or delayed, which could hurt our business and cause our stock price to decline. In addition, our relationships with these companies may not be successful. Disputes may arise with our collaborators, including disputes over ownership rights to intellectual property, know-how or technologies developed with our collaborators. We may not be able to negotiate similar additional arrangements in the future to develop and commercialize ZADAXIN or other products.

We may lose market share or otherwise fail to compete effectively in the intensely competitive biopharmaceutical industry.

Competition in the biopharmaceutical industry is intense, and we expect that competition will increase. Our success depends on our ability to compete in this industry, but we cannot assure you that we will be able to successfully compete with our competitors. Increased competitive pressure could lead to intensified price-based competition resulting in lower prices and margins, which would hurt our operating results.

We are focused on developing ZADAXIN as a treatment for HCV and HBV and certain cancers. Several large biopharmaceutical companies have substantial commitments to interferon alpha, an approved drug for treating HBV and HCV, and to lamivudine and adefovir, approved drugs to treat HBV. We cannot assure you that we will compete successfully against our competitors or that our competitors, or potential competitors, will not develop drugs or other treatments for HCV, HBV, cancer and other diseases that will be superior to ours.

If third-party reimbursement is not available or patients cannot otherwise pay for ZADAXIN, we may not be able to successfully market ZADAXIN.

Significant uncertainty exists as to the reimbursement status of new therapeutic products, such as ZADAXIN. We cannot assure you that third-party insurance coverage and reimbursement will be available for therapeutic products we might develop. The failure to obtain third-party reimbursement for our products, particularly in the United States, Europe and Japan, would harm our business. Further, we cannot assure you that additional limitations will not be imposed in the future in the United States on drug coverage and reimbursement due to proposed health care reforms. In many emerging markets where we have marketing rights to ZADAXIN, but where government resources and per capita income may be so low that our products will be prohibitively expensive, we may not be able to market our products on economically favorable terms, if at all.

Efforts by governmental and third-party payers to contain or reduce health care costs or the announcement of legislative proposals or reforms to implement government controls could cause us to reduce the prices at which we market our drugs, which will reduce our gross margins and may harm our business.

Settlements regarding our claims relating to the Japanese clinical trials may not be favorable

Based on recent information received from Schering Plough KK (SPKK) and in conjunction with SciClone's own investigative efforts, SciClone has determined that it cannot submit a Japanese new drug application (JNDA), or apply for a pre-JNDA preliminary review, for ZADAXIN as a therapy for hepatitis B to the Ministry of Health in Japan. This conclusion is based on SPKK's failure to conduct certain audits and generate certain reports during the pre-2001 studies that it managed and SciClone's conclusion that such documentation probably cannot be created at this time. This conclusion is not based on the substantive results of the Japan trials, which showed ZADAXIN to have competitive efficacy and safety in the treatment of hepatitis B. SciClone and SPKK continue to investigate and discuss the issues involved, and how this matter should be fairly resolved. However, should these discussions not conclude to SciClone's satisfaction, SciClone is prepared to take legal action against SPKK. SciClone is now determining the appropriate development strategy for ZADAXIN in Japan, however, it is unlikely that SciClone will be able to submit a JNDA for ZADAXIN in Japan for some years. This entire process could be lengthy and could incur significant management time and expense.

We may be subject to product liability lawsuits, and our insurance may be inadequate to cover damages.

Clinical trials or marketing of any of our current and potential products may expose us to liability claims from the use of these products. We currently carry product liability insurance. However, we cannot be certain that we will be able to maintain insurance on acceptable terms, if at all, for clinical and commercial activities or that the insurance would be sufficient to cover any potential product liability claim or recall. If we fail to have sufficient coverage, our business, results of operations and cash flows could be adversely affected.

We depend on international sales, and global conditions could negatively affect our operating results.

A large majority of our sales are in China. Heightened tensions resulting from the current geopolitical conditions in the Middle East, North Korea and elsewhere could worsen, causing disruptions in foreign trade, which would harm our sales. In particular, our commercial product is manufactured in Europe and distributed by us from our operations in Hong Kong. Any disruption of our supply and distribution activities due to geopolitical conditions could decrease our sales and harm our operating results.

If we are unable to comply with environmental and other laws and regulations, our business may be harmed.

We are subject to various federal, state and local laws, regulations and recommendations relating to the use, manufacture, storage, handling and disposal of hazardous materials and waste products (including radioactive compounds and infectious disease agents), as well as safe working conditions, laboratory and manufacturing practices and the experimental use of animals. The extent of government regulation that might result from future legislation or administrative action in these areas cannot be accurately predicted.

We do not currently maintain hazardous materials at our facilities. While we outsource our research and development programs involving the controlled use of biohazardous materials, if in the future we conduct these programs ourselves, we might be required to incur significant cost to comply with environmental laws and regulations. Further, in the event of an accident, we would be liable for any damages that result, and the liability could exceed our resources.

Our stock price may be volatile, and an investment in our stock could suffer a decline in value.

The market price of our common stock has experienced, and may continue to experience, substantial volatility due to many factors, some of which we have no control over, including:

- progress and results of clinical trials involving ZADAXIN;
- progress of ZADAXIN through the regulatory process, especially regulatory actions and the adequacy of clinical data and documentation for regulatory purposes in the United States, Europe and Japan;
- timing and achievement of milestones;
- announcements of technological innovations or new products by us or our competitors;
- government regulatory action affecting our drug products or our competitors' drug products in both the United States and foreign countries;

- developments or disputes concerning patent or proprietary rights;
- changes in company assessments or financial estimates by securities analysts;
- actual or anticipated fluctuations in our quarterly operating results;
- changes in assessments of our internal controls over financial reporting;
- general stock market conditions and fluctuations for the emerging growth and biopharmaceutical market sectors;
- economic conditions in the United States or abroad; and
- broad financial market fluctuations in the United States, Europe or Asia.

In the past, following periods of large price declines in the public market price of a company's securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of our attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

Substantial sales of our stock or the exercise or conversion of options or convertible securities may impact the market price of our common stock.

As of June 30, 2005, stock options to purchase 7,487,092 shares of common stock were outstanding, of which options to purchase 4,614,950 shares were exercisable. Also, as of the same date two notes convertible into a total of 684,140 shares of common stock were outstanding. The note holder has the right to purchase up to $8.3 million of additional convertible notes due on or before March 2006, which, if fully issued, will be convertible into an additional 684,140 shares of our common stock. Upon exercise of options or conversion of the notes, these issued shares of common stock will be freely tradable.

Future sales of substantial amounts of our common stock could adversely affect the market price of our common stock. Similarly, if we raise additional funds through the issuance of common stock or securities convertible into or exercisable for common stock, the percentage ownership of our present stockholders will be reduced and the price of our common stock may fall.

Sales of our common stock by officers and directors could affect our stock price.

Our Board of Directors has approved an amendment to our trading policy that permits officers and directors to enter into trading plans that comply with the requirements of Rule 10b5-1 of the Securities and Exchange Act of 1934. Rule 10b5-1 allows corporate officers and directors to adopt written, pre-arranged stock trading plans when they do not have material, non-public information. Using these plans, officers and directors can gradually diversify their investment portfolios, can spread stock trades out over an extended period of time to reduce any market impact and can avoid concerns about initiating stock transactions at a time when they might be in possession of material, non-public information. As of August 2, 2005, one director has adopted such a plan, and other directors or officers may do so in the future. We expect future sales by officers and directors either under 10b5-1 plans or otherwise as a result of their personal financial planning. We do not believe the volume of such sales would affect our trading price; however, the market could react negatively to sales by our officers and directors, which could affect the trading price of our stock.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to the stockholders. Prior to our reincorporation in Delaware, we had a stockholder rights plan, also commonly known as a "poison pill," which we terminated in connection with the reincorporation. We currently do not intend to adopt a stockholder rights plan. However, our charter documents do contain certain anti-takeover provisions, including provisions in our certificate of incorporation providing that stockholders may not cumulate votes, stockholders' meetings may be called by stockholders only if they hold 25% or more of our common stock and provisions in our bylaws providing that the stockholders may not take action by written consent. Additionally, our board of directors has the authority to issue 10 million shares of preferred stock and to determine the terms of those shares of stock without any further action by the stockholders. The rights of holders of our common stock are subject

to the rights of the holders of any preferred stock that may be issued. The issuance of preferred stock could make it more difficult for a third-party to acquire a majority of our outstanding voting stock. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future.

New accounting pronouncements may impact our operations and financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and this may lead to changes in our accounting policies in the future. One such new pronouncement issued in December 2004 by the Financial Accounting Standards Board ("FASB") is FASB Statement No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"). SFAS 123R requires share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values. We expect to adopt SFAS 123R on January 1, 2006. The Company currently accounts for share-based payments to employees and directors using Accounting Principles Board Opinion 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee and director stock options and employee stock purchase plans. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our results of operations, although it will have no impact on our cash or overall financial position.

New legislation may impact our financial position or results of operations.

Compliance with changing regulations concerning corporate governance and public disclosure has resulted in and may continue to result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ National Market rules, are creating uncertainty for companies such as ours and costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment has and may continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

We may be subject to currency exchange rate fluctuations, which could adversely affect our financial performance.

Substantially all of our product sales are denominated in U.S. dollars. Fluctuation in the U.S. dollar exchange rate with local currency directly affects the customer's cost for our product. In particular, a stronger U.S. dollar vis-à-vis the local currency would tend to have an adverse effect on sales and potentially on collection of accounts receivable. Through the periods ended June 30, 2005, this exposure to currency exchange rate fluctuations has been minimal because the Chinese currency has been pegged to the U.S. dollar. However, the Chinese currency is no longer pegged to the U.S. dollar and consequently, our foreign operations may expose us to greater risk of decreased sales due to currency exchange rate fluctuations in the future. In addition, we are subject to currency exchange rate fluctuations as a result of expenses incurred by our foreign operations. In particular, one of our supply arrangements under which we purchase finished products is denominated in euros and costs of our marketing efforts in China are paid in local currency. Consequently, changes in exchange rates could unpredictably and adversely affect our operating results and could result in exchange losses. To date, we have not hedged against the risks associated with fluctuations in exchange rates and, therefore, exchange rate fluctuations could have a material adverse impact on our future operating results and stock price.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest primarily in U.S. Treasury or U.S. government agency notes. Our investments in these notes are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in short-term notes and maintain an average maturity of less than one year. A hypothetical 60 basis point increase in interest rates would result in an approximate $187,794 decrease (0.6%) in fair value of our available-for-sale securities. This potential change is based on sensitivity analyses performed on our financial position at June 30, 2005. Actual results may differ materially.

Substantially all our sales and most of our manufacturing costs to date have been in U.S. dollars and our foreign currency exchange rate losses to date have been insignificant. Our purchases from one of our contract manufacturers, however, are denominated in euros and this exposes us to foreign currency rate fluctuations. Consequently, changes in exchange rates could unpredictably and adversely affect our operating results and could result in significant exchange rate losses. To date, we have not hedged against the risks associated with fluctuations in exchange rates and, therefore, exchange rate fluctuations could have a material adverse impact on our future operating results and stock price.

Item 4. Controls and Procedures

As of the end of the fiscal quarter ended June 30, 2005, SciClone carried out an evaluation, under the supervision and with the participation of members of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of SciClone's disclosure controls and procedures pursuant to Rule 13a-15(b) of the Securities Exchange Act of 1934. Based on this evaluation our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2005 our disclosure controls and procedures, designed to ensure that information related to SciClone and our consolidated subsidiaries is recorded, processed, and reported timely and is accumulated and made known to our Chief Executive Officer and Chief Financial Officer to allow timely decisions regarding required disclosures, were not effective due to the material weakness in our internal controls over financial reporting discussed below.

In relation to the quarter ended June 30, 2005, we identified a material weakness in our internal controls over financial reporting as defined in Public Company Accounting Oversight Board ("PCAOB") Standard No. 2. This material weakness related to our failure, due to our lack of familiarity with certain technical stock option accounting matters, to evaluate the correct accounting effect of a stock price performance based option granted to our Chief Executive Officer on June 1, 2005, the date he commenced his employment. We had not previously granted any stock price performance based options. Due to the terms of this option, Accounting Principles Board Opinion No. 25 (“APB 25”) requires the application of variable accounting and specifically requires the recognition of non-cash expense in the period that portions of the option vest or are deemed probable of vesting at the end of the reporting period. The vesting of this option is directly determined by the price level of trading activity in our stock, and the conditions required to recognize a related non-cash expense did not occur in the interim period ended June 30, 2005. However, had the conditions required the recognition of a non-cash expense related to this option under APB 25, our accounting procedures at June 30, 2005 would not have correctly applied APB 25. In August 2005 we improved the processes covering equity transactions and continuous compliance review by the Director of Finance. We are continuing to strengthen our internal control procedures to ensure that all aspects of our financial reporting process, including APB 25 and Statement of Financial Accounting Standards No. 123 application, are reviewed and approved by our Director of Finance to evidence full compliance with U.S. generally accepted accounting principles. In addition, we will consider contracting additional consultants in our accounting and reporting function as we believe appropriate, and have updated our contract and agreement approval policy to enhance our internal controls.

Our disclosure controls and procedures are designed to ensure that the information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and to reasonably assure that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met under all potential conditions, regardless of how remote, and may not prevent or detect all error and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within SciClone have been detected.

We continue to improve and refine our internal controls as an ongoing process. Other than as summarized above, there have been no changes in our internal controls over financial reporting or other factors that have materially affected, or are reasonably likely to materially affect, our internal controls.

PART II. OTHER INFORMATION

Item 4. Submission of Matters to a Vote of Security Holders

We held our Annual Meeting of Stockholders on June 7, 2005 to elect six (6) directors, to approve the amendment to the Company's 2004 Stock Option Plan to increase the maximum aggregate number of shares that may be issued thereunder, to approve the amendment and restatement of the Company's 2004 Stock Option Plan as the 2005 Equity Incentive Plan, to approve the amendment of the Company's 2004 Outside Directors Stock Option Plan to increase the maximum aggregate number of shares that may be issued thereunder, and to ratify Ernst & Young LLP as the Company's independent auditors for fiscal 2005.

At the Annual Meeting of Stockholders, all of the director nominees were elected by the following number of votes:

	For	Votes Withheld
Dean S. Woodman	34,711,651	3,234,121
John D. Baxter, M.D.	33,707,420	4,238,352
Richard J. Hawkins	34,677,430	3,268,342
Rolf H. Henel	34,695,145	3,250,627
Ira D. Lawrence, M.D.	35,702,107	2,243,665
Jon S. Saxe	33,956,273	3,989,499

Stockholders approved the amendment to the Company's 2004 Stock Option Plan to increase the maximum aggregate number of shares that may be issued thereunder by 2,300,000 shares from 2,500,000 shares to 4,800,000 shares by the following number of votes: 11,275,906 for; 7,986,223 against; 119,908 abstaining; and 18,563,735 broker non-votes.

Stockholders approved the amendment and restatement of the Company's 2004 Stock Option Plan as the 2005 Equity Incentive Plan by the following number of votes: 13,571,940 for; 5,696,015 against; 114,082 abstaining; and 18,563,735 broker non-votes.

Stockholders approved the amendment of the Company's 2004 Outside Directors Stock Option Plan to increase the maximum aggregate number of shares that may be issued thereunder by 550,000 shares from 465,000 shares to 1,015,000 shares by the following number of votes: 11,116,450 for; 8,126,943 against; 138,644 abstaining; and 18,563,735 broker non-votes.

Stockholders ratified Ernst & Young LLP as the Company's independent auditors for fiscal 2005 by the following number of votes: 36,207,250 for; 1,615,232 against; and 123,290 abstaining.

Item 6. Exhibits

Exhibit Number	Description
3(i).1[(1)]	Amended and Restated Certificate of Incorporation.
3(ii).1[(1)]	Bylaws.
4.1[(2)]	Rights Agreement dated as of July 25, 1997 between the Registrant and Chase Mellon Shareholder Services, LLC.
4.2[(1)]	First Amendment to Rights Agreement dated as of July 17, 2003 between the Registrant and Mellon Investor Services LLC.
4.3[(3)]*	6% Convertible Note dated as of December 7, 2000 by the Registrant in favor of UBS AG, London Branch.
4.4[(3)]*	Option Agreement dated as of October 26, 2000 by and between the Registrant and UBS AG, London Branch.
4.5[(3)]*	Amendment No. 1 to Option Agreement dated as of December 19, 2000 by and between the Registrant and UBS AG, London Branch.

4.6[(4)]*	6% Convertible Note dated as of March 21, 2001 by the Company in favor of UBS AG, London Branch.
4.7[(4)]*	Option Agreement dated as of February 16, 2001 by and between the Company and UBS AG, London Branch.
4.8[(4)]*	Amendment No.1 to Option Agreement dated as of March 21, 2001 by and between the Company and UBS AG, London Branch.
10.1[(5)]	Employment Agreement between SciClone Pharmaceuticals, Inc. and Ira D. Lawrence, M.D. dated as of April 25, 2005.
10.2[(5)]	Change in Control Agreement between SciClone Pharmaceuticals, Inc. and Ira D. Lawrence, M.D. dated as of April 25, 2005.
10.3[(5)]	Indemnity Agreement between SciClone Pharmaceuticals, Inc. and Ira D. Lawrence, M.D. dated as of April 25, 2005.
10.4[(6)]	Amendment of Stock Option Agreement between SciClone Pharmaceuticals, Inc. and Jere E. Goyan, Ph.D. dated as of May 29, 2005.
10.5[(6)]	Amendment of Stock Option Agreement between SciClone Pharmaceuticals, Inc. and Edwin C. Cadman, M.D. dated as of May 29, 2005.
10.6[(7)]	SciClone Pharmaceuticals, Inc. 2005 Equity Incentive Plan, as effective as of June 7, 2005.
10.7[(7)]	SciClone Pharmaceuticals, Inc. 2004 Outside Directors Stock Option Plan, as amended June 7, 2005.
31.1[(8)]	Rule 13a-14(a) Certification of Chief Executive Officer.
31.2[(8)]	Rule 13a-14(a) Certification of Chief Financial Officer.
32.1[(8)]	Section 1350 Certification of Chief Executive Officer.
32.2[(8)]	Section 1350 Certification of Chief Financial Officer.

*Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4), 200.83 and 230.46.

(1) Incorporated by reference from the Company's Current Report on Form 8-K filed on July 28, 2003.
(2) Incorporated by reference from the Company's Current Report on Form 8-K filed on October 14, 1997.
(3) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2000.
(4) Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed on May 15, 2001.
(5) Incorporated by reference from the Company's Current Report on Form 8-K filed on April 29, 2005.
(6) Incorporated by reference from the Company's Current Report on Form 8-K filed on June 1, 2005.
(7) Incorporated by reference from the Company's Current Report on Form 8-K filed on June 17, 2005.
(8) Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SCICLONE PHARMACEUTICALS, INC.
(Registrant)

Date: August 9, 2005

/s/ Richard A. Waldron

Richard A. Waldron
Chief Financial Officer
(Principal Financial & Accounting Officer)

INDEX TO EXHIBITS

Exhibit Number	Exhibit	Sequentially Numbered Page
3(i).1[(1)]	Amended and Restated Certificate of Incorporation.....	
3(ii).1[(1)]	Bylaws.	
4.1[(2)]	Rights Agreement dated as of July 25, 1997 between the Registrant and Chase Mellon Shareholder Services, LLC.	
4.2[(1)]	First Amendment to Rights Agreement dated as of July 17, 2003 between the Registrant and Mellon Investor Services LLC.	
4.3[(3)*]	6% Convertible Note dated as of December 7, 2000 by the Registrant in favor of UBS AG, London Branch.	
4.4[(3)*]	Option Agreement dated as of October 26, 2000 by and between the Registrant and UBS AG, London Branch.	
4.5[(3)*]	Amendment No. 1 to Option Agreement dated as of December 19, 2000 by and between the Registrant and UBS AG, London Branch.	
4.6[(4)*]	6% Convertible Note dated as of March 21, 2001 by the Company in favor of UBS AG, London Branch.	
4.7[(4)*]	Option Agreement dated as of February 16, 2001 by and between the Company and UBS AG, London Branch.	
4.8[(4)*]	Amendment No. 1 to Option Agreement dated as of March 21, 2001 by and between the Company and UBS AG, London Branch.	
10.1[(5)]	Employment Agreement between SciClone Pharmaceuticals, Inc. and Ira D. Lawrence, M.D. dated as of April 25, 2005.	
10.2[(5)]	Change in Control Agreement between SciClone Pharmaceuticals, Inc. and Ira D. Lawrence, M.D. dated as of April 25, 2005.	
10.3[(5)]	Indemnity Agreement between SciClone Pharmaceuticals, Inc. and Ira D. Lawrence, M.D. dated as of April 25, 2005.	
10.4[(6)]	Amendment of Stock Option Agreement between SciClone Pharmaceuticals, Inc. and Jere E. Goyan, Ph.D. dated as of May 29, 2005.	
10.5[(6)]	Amendment of Stock Option Agreement between SciClone Pharmaceuticals, Inc. and Edwin C. Cadman, M.D. dated as of May 29, 2005.	
10.6[(7)]	SciClone Pharmaceuticals, Inc. 2005 Equity Incentive Plan, as effective as of June 7, 2005.	
10.7[(7)]	SciClone Pharmaceuticals, Inc. 2004 Outside Directors Stock Option Plan, as amended June 7, 2005.	
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31.2[(8)]	Rule 13a-14(a) Certification of Chief Financial Officer.	
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